

EXHIBIT B

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE METFORMIN MARKETING AND
SALES PRACTICES LITIGATION

Civil Action No. 20-2324

ORDER

THIS MATTER comes before the Court on the Manufacturer Defendants’ and Pharmacy Defendants’¹ Motions to Dismiss pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6), ECF Nos. 78 & 80;

and it appearing that Plaintiffs² oppose the Motions, ECF No. 95;

and it appearing that this putative class action arises out of the allegedly adulterated, misbranded, and/or unapproved manufacturing, sale, and distribution of metformin-containing drugs (“MCDs”) by Defendants, see generally Am. Compl., ECF No. 58;

and it appearing that Metformin is the leading drug used in the treatment and management of type 2 diabetes and is the fourth most prescribed drug in the United States, id. ¶¶ 2, 4;

¹ This consolidated putative class action is brought against two groups of Defendants: manufacturers and pharmacies. First, Plaintiffs bring this action against sixteen manufacturers (the “Manufacturer Defendants”). Of those sixteen, eleven joined the Manufacturer Defendants’ Motion: Actavis, LLC, Actavis Pharma, Inc., Amneal Pharmaceuticals LLC, Ascend Laboratories, LLC, Aurobindo Pharma USA, Inc., Aurolife Pharma, LLC, Granules Pharmaceuticals, Inc., Granules USA, Inc. Heritage Pharmaceuticals, Inc d/b/a Avent Pharmaceuticals Inc., and Teva Pharmaceuticals USA Inc. See ECF No. 78. Amneal Pharmaceuticals Inc. and AvKARE Inc. have since joined the Motion. ECF No. 87. Second, Plaintiffs bring this action against four named pharmacies (the “Pharmacy Defendants”), three of which have joined the Pharmacy Defendants’ motion to dismiss: CVS Pharmacies, Inc. (plead as CVS Health Corporation), Walgreens Boot Alliance, Inc., and Rite-Aid Corporation. See ECF No. 80, 89, 103. Although not a Pharmacy Defendant, AvKARE Inc. similarly joins the Pharmacy Defendants’ Motion in part.

² There are eight proposed Class Representative Plaintiffs in the instant action. First, seven Plaintiffs seek to represent the interests of consumers who purchased Defendants’ MCDs (the “Consumer Plaintiffs”): Joseph Brzozowski and Jacqueline Harris (citizens and residents of New Jersey), Michael Hann, Mohammad Rahman, and Elaine Wohlmut (citizens and residents of California), Stelios Mantalis (citizen and resident of New York), and Kristin Wineinger (citizen and resident of Indiana). Second, one Plaintiff, MSP Recover Claims, Series LLC (“MSPRC”), seeks to represent the interests of third-party payors (“TPPs”) who made co-payments for Defendants’ MCDs.

and it appearing that the Manufacturer Defendants allegedly manufactured—or are closely affiliated with entities that manufactured—MCDs that were contaminated with a probable human carcinogen known as N-nitrosodimethylamine (“NDMA”), *id.* ¶¶ 6, 28;

and it appearing that Plaintiffs bring this action on behalf of millions of MCD consumers as well as third-party payors (“TPPs”) who bought or made reimbursements for the Manufacturer Defendants’ MCDs that were rendered worthless as a result of the NDMA contamination, *id.* ¶ 6;

and it appearing that the Consumer Plaintiffs each allege that they “paid money for one or more of Defendants’ MCDs,” and that despite it being warranted that the MCDs were the same as the brand drug (known as the “reference listed drug” or “RLD”), they received “a product that was not the same” as the RLD, *id.* ¶¶ 12-18;

and it appearing that MSPRC alleges that it was assigned the rights and claims to recovery of TPPs who made payments for Defendants’ allegedly adulterated drugs, *id.* ¶¶ 19-27;

and it appearing that Plaintiffs further contend that they sustained economic damages because they “paid for or made reimbursements for generic MCDs that were illegally and willfully introduced into the market by Defendants,” *id.* ¶ 11;

and it appearing that Defendants now move to dismiss Plaintiffs’ Amended Complaint, arguing, among other things, that Plaintiffs lack standing, ECF Nos. 78 & 80;³

³ A motion to dismiss for lack of standing is properly brought pursuant to Rule 12(b)(1). *See Bellentine v. United States*, 486 F.3d 806, 810 (3d Cir. 2007). Under Rule 12(b)(1), a plaintiff bears the burden of persuading the Court that subject matter jurisdiction exists. *See Kehr Packages, Inc. v. Fidelcor, Inc.*, 926 F.2d 1406, 1409 (3d Cir. 1991). In resolving a Rule 12(b)(1) motion, a court first determines whether the motion presents a “facial” or “factual” attack. *See Constitution Party of Pa. v. Aichele*, 757 F.3d 347, 357 (3d Cir. 2014). A facial attack argues that a claim on its face “is insufficient to invoke the subject matter jurisdiction of the court,” *id.* at 358, and “does not dispute the facts alleged in the complaint,” *Davis v. Wells Fargo*, 824 F.3d 333, 346 (3d Cir. 2016). A court reviewing a facial attack must “consider the allegations of the complaint and documents referenced therein and attached thereto, in the light most favorable to the plaintiff.” *Constitution Party of Pa.*, 757 F.3d at 358. Here, Defendants’ motions to dismiss for lack of standing present facial attacks because they challenge Plaintiffs’ standing to bring this lawsuit according to the pleaded facts. *See* Mfr. Def. Mem. at 13-20, ECF No. 78.1; Pharmacy Def. Mem. at 12-15, ECF No. 80.1. The Court thus accepts the pleaded facts as they relate to Plaintiffs’ standing as true and draws all reasonable inferences in Plaintiffs’ favor. *See Constitution Party of Pa.*, 757 F.3d at 358.

and it appearing that a litigant seeking to invoke federal jurisdiction must establish that they have standing to sue, Lujan v. Defs. of Wildlife, 504 U.S. 555, 561 (1992);

and it appearing that a plaintiff has standing if they have “(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable decision,” Spokeo, Inc. v. Robins, 136 S. Ct. 1540, 1547 (2016) (citing Lujan, 504 U.S. at 560-61);

and it appearing that Plaintiffs lack standing for two reasons;

and it appearing that first, the Consumer Plaintiffs have failed to demonstrate that they suffered an injury as they have not alleged that they purchased or ingested any MCDs containing NDMA;

and it appearing that although each Consumer Plaintiff alleges that they bought a product that was not the same as the RDL and that was “illegally and willfully introduced into the market by Defendants,” Am. Compl. ¶¶ 11-18, they do not allege that they purchased NDMA-contaminated MCDs from Defendants;⁴

and it appearing that instead the Consumer Plaintiffs seek to bring this action “on behalf of” the consumers who paid for “Defendants’ MCDs [that] were adulterated and/or misbranded . . . through contamination with [NDMA],” id. ¶ 6;

and it appearing, however, that a class representative must show that they themselves suffered an injury and cannot merely rely upon the standing of individuals in the proposed class, see Spokeo, 136 S. Ct. at 1547 n.6 (2016) (explaining that class action suits maintain the same injury-in-fact requirement as every other case: each class representative “must allege and show

⁴ In contrast, MSPRC has adequately alleged that it suffered an injury, as it contends that it was assigned the rights of certain TPPs who made payments for the Manufacturer Defendants’ MCDs contaminated with NDMA. Am. Compl. ¶ 27. In support, MSPRC provides examples of the payments that were made by its assignors. See id.

that they personally have been injured, not that injury has been suffered by other unidentified members of the class to which they belong”) (internal quotation marks and citations omitted);

and it appearing that the Consumer Plaintiffs have thus failed to allege that they suffered an injury;⁵

and it appearing that second, Plaintiffs have not shown causation because they have failed to connect each Defendants’ actions to at least one injured Plaintiff, see Cent. States Se. & Sw. Area Health & Welfare Fund v. Merck-Medco Managed Care, LLC, 504 F.3d 229, 241 (2d Cir. 2015) (“To establish Article III standing in a class action, it is not required that each named plaintiff must have a claim against each named defendant. Rather, for every named defendant there must be at least one named plaintiff who can assert a claim directly against that defendant. . . .”) (quoting 1 Newberg on Class Actions § 2:6 n.3 (4th ed. 2002));

and it appearing that no Consumer Plaintiff alleges (1) which Manufacturer Defendant’s drug they purchased, or (2) at which Pharmacy Defendant they purchased their drugs, so the Court, therefore, cannot link each Defendant to any injury suffered by any Consumer Plaintiff;

and it appearing that although MSPRC alleges that the TPPs who assigned their rights to MSPRC made payments for the Manufacturer Defendants’ adulterated drugs, they too do not allege any involvement by the Pharmacy Defendants;

and it appearing that Plaintiffs have thus failed to show causation;⁶

⁵ The Consumer Plaintiffs contend that they plausibly allege that they bought an MCD contaminated with NDMA. The Court disagrees. A complaint must “state, clearly and concisely, the injury suffered by each Plaintiff as a result of the alleged wrongs committed by defendants.” El Ameen Bey v. Stumpf, 825 F. Supp. 2d 537, 560 (D.N.J. 2011). By failing to allege that they bought one of Defendants’ MCDs contaminated with NDMA, Plaintiffs have not adequately alleged any injury suffered.

⁶ Plaintiffs argue that they may plead different defendants caused harm “in the alternative” under Federal Rule of Civil Procedure 8(d). But Plaintiffs do not plead “in the alternative;” rather, Plaintiffs fail to allege that any Defendant caused them harm. Plaintiffs also cite to In re Asacol Antitrust Litig., 907 F.3d 42 (1st Cir. 2018), for the proposition that named plaintiffs in a class action have standing to assert claims on behalf of absent class members in other states. This is true, but the named plaintiffs still must establish their own standing as a threshold matter. Finally, the majority of Plaintiffs’ opposition focuses on the fact that a plaintiff need not prove direct, proximate harm to establish

IT IS on this 20th day of May, 2021;

ORDERED that Defendants' Motions to Dismiss for lack of standing, ECF Nos. 78 & 80, are **GRANTED**; and it further

ORDERED that to the extent Plaintiffs can cure the deficiencies identified in this order, they may file amended pleadings within thirty (30) days.

/s Madeline Cox Arleo
HON. MADELINE COX ARLEO
UNITED STATES DISTRICT JUDGE

traceability, but rather can rely upon indirect harm. Again, this is beside the point. Plaintiffs here do not allege facts suggesting that any of the Defendants caused, directly or indirectly, their alleged injury.